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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,162	11/19/2003	Hsing-Wen Sung	S&T-125	6771

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,162	SUNG, HSING-WEN	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1, 15, and 17 are pending and the subject of this Office Action. Claims 2-14, 16, and 18-41 were cancelled in the Applicants' response filed on 19 December 2007.

Claim Rejections – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this office action:

> (a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 15, and 17 are rejected under 35 U.S.C. §103(a) as being obvious over Buscemi et al in view of U.S. Patent No. 5,272,172 [hereinafter referred to as "Fujii et al"] as evidenced by Vaya, Ampara, et al., "Red Blood Cell Aggregartion and Primary Hyperlipoproteinemia," 15 October 1993, *Thrombosis Research*, Vol. 72, Issue 2, 15 October 1993, pages 119-126 (Abstract as included, rather than article in its entirety is primary reference).

The invention in Buscemi et al is a biodegradable stent, saturated with drugs, that has a matrix strengthened by, for example, polylactic acid (Col. 3, lines 44-49). The tubular main body of the stent includes an outer and an inner surface (Col. 4, lines 21-23). The main body of

the stent includes a film covering the inner surface, which is formed by conventional methods such as solution casting (Col. 5, lines 14-18). The biodegradable materials for the main body of the stent include polyglycolic acid, polylactic acid, polycaprolactone, collagen or other connective proteins, and/or copolymers of these materials as well as composites and combinations (Col. 6, lines 11-30).

Buscemi et al also disclose that drugs are incorporated into the stent using techniques known in the art such as simple mixing or solubilizing with polymer solutions or coating onto an already formed film or fiber, etc. (Col. 12, lines37-43). The fibers can contain anti-thrombogenic drugs and also, drugs or biologically active agents can be incorporated to the film layer, promoting release of drugs or agents at different rates (Col. 12, lines 47-58), including aspirin, tissue plasminogen activators, growth factors, thromboxane inhibitors, growth factors, genetic materials and complete expression genes, etc (Col. 12, lines 64-67 through Col. 13, lines 1-10). Buscemi et al also disclose inhibit or control the formation of thrombus or thrombolytics, and prevent smooth muscle cell growth on the inner surface wall of vessels (Col. 12, lines 59-66).

Fujii et al teach that "Cape Jasmim (*jasminoides Ellis*) … has long been known to have pharmacological effects such as an anti-arteriosclerosis agent, a blood coagulation inhibitor and a cholagogue, and geniposide as a typical active component of Cape Jasmim" (Col. 1, lines 19-24). Fujii et al also teach iridoid derivatives and their pharmacologically permissible salts, including for example, methyl (4aS, 7aS)-6,7-expoxy-1, 4a, 5, 6, 7, 7a-hexahydro-1-hydroxy-7-(hydroxymethyl)-cyclopenta[c]pyran-4-carboxylate (Col. 5, lines 42-43), to be anti-hyperlipemia drugs and to have cholagogue actions (Col. 1, lines 39-52).

Applicant argues that Cape Jasmim has different chemical and structural properties when compared to genipin or epoxy compounds, as the latter do not exert any pharmaceutical effects to the biodegradable stent and further, ApoA-I Milano/phopsholipid complexes and lipostabil are unobvious over the instant references. Albeit Applicant advances these positions, they remain unsubstantiated and therefore are but allegations lacking factual support. And to the contrary, both genipin and geniposide are notably classified as carboxylic acid glucosides. *Please see* National Library of Medicine – Medical Subject Headings, 2008 Cataloguing Information, The National Institutes of Health (2008), entries for genipin and geniposide.

As noted in the prior Office Action, it is well-understood in the pharmaceutical art that hypercholesterolemia and hyperlipemia share common etiologies. *Please see* Vaya, Ampara, et al. (Abstract). Furthermore, it is well-understood that in evaluating the same, the following parameters are usually measured: "fibrinogen (Fbg), plasmatic lipids, apolipoproteins, glucose, HbA_1c and membrane erythrocyte lipids: cholesterol (C) and phospholipids (PL)." *Id.* Furthermore, it is understood that there is a direct correlation between erythrocyte aggregation with fibrinogen and apolipoproteins. *Id.*

Due to the overlapping subject matter of treating atherosclerotic and hyperlipidemic conditions resultant from erythrocyte aggregation, one of ordinary skill in the art would be motivated to combine the teachings of Buscemi et al with the teachings of Fujii et al to conclude that a biodegradable stent with medications containing genipin or an epoxy compound, or a biological material to treat hypercholesterolemia would be *prima facie* obvious over prior art.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see

http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/

Primary Examiner, Art Unit 1614